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Commissioner NAME	United States Patent and Trademark Office COMPANY/FIRM	703-872-9306 FAX NUMBER
CITY	STATE	703-808-1235 (TELEPHONE NUMBER)

**FROM:**

Patrea L. Pabst NAME	404-817-8473 TELEPHONE	15 TOTAL PAGES (Including Cover Sheet)
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**FOR THE RECORD:**

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**MESSAGE:**

Applicant: Christopher William Ogden, James Adshead, Anna Maria Kessling, and Bijan Khoubehi

Serial No.: 09/933,548 Art Unit: 1634

Filed: August 20, 2001 Examiner: S.A. Sakelaris

For: **DIAGNOSIS AND TREATMENT OF PROSTATE CANCER**

# 1249892\_v1

PTO/SB/21 (01-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	09/933,548	
	Filing Date	August 20, 2001	
	First Named Inventor	Christopher W. Ogden	
	Art Unit	1634	
	Examiner Name	S. A. Sakelaris	
Total Number of Pages in This Submission	14	Attorney Docket Number	NORT 100

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/Declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Petition for Reconsideration of Restriction Requirement
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Firm or Individual	Patricia L. Pabst Esq., Reg. No. 31,284 Holland & Knight LLP	
Signature	Suite 2000, One Atlantic Center; 1201 West Peachtree Street, N.E.; Atlanta, GA 30309-3400	
Date	October 1, 2003	

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Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 100.00)

**Complete if Known**

Application Number	09/933,548
Filing Date	August 20, 2001
First Named Inventor	Christopher William Ogden et al
Examiner Name	S. A. Sakelaris
Art Unit	1634
Attorney Docket No.	NORT 100

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number  
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**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 750	2001 375	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 520	2003 260	Plant filing fee	
1004 750	2004 375	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from below	Fee Paid
40	-47	0	0
9	-10**	0	0

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1202 18	2202 9	Claims in excess of 20	
1201 84	2201 42	Independent claims in excess of 3	
1203 280	2203 140	Multiple dependent claim, if not paid	
1204 84	2204 42	** Reissue independent claims over original patent	
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$)

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**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	2053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 410	2252 205	Extension for reply within second month	
1253 930	2253 465	Extension for reply within third month	
1254 1,450	2254 725	Extension for reply within fourth month	
1255 1,970	2255 985	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,300	2453 650	Petition to revive - unintentional	
1501 1,300	2501 650	Utility issue fee (or reissue)	
1502 470	2502 235	Design issue fee	
1503 630	2503 315	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	100.00
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1808 180	1808 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 750	2809 375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 750	2810 375	For each additional invention to be examined (37 CFR 1.129(b))	
1801 750	2801 375	Request for Continued Examination (RCE)	
1802 900	900	Request for expedited examination of a design application	

Other fee (specify)

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**SUBMITTED BY**

Name (Print/Type) Patrea L. Peabst

Registration No. (Attorney/Agent)

31,284

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October 1, 2003

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Christopher William Ogden, James Adshead, Anna Maria Kessling, and  
Bijan Khoubehi

Serial No.: 09/933,548

Group Art Unit: 1634

Filed: August 20, 2001

Examiner: S.A. Sakelaris

For: *DIAGNOSIS AND TREATMENT OF PROSTATE CANCER*

Assistant Commissioner for Patents  
Washington, D.C. 20231

**PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT**

Sir:

Pursuant to 37 C.F.R. § 1.144, applicants petition the Group Director to review the restriction requirement set forth in the Office Action mailed on April 22, 2003, as maintained in the office action mailed July 1, 2003. No fee is believed to be due. However, the Commissioner is authorized to charge any fees that may be required to our Deposit Order Account No. 50-1868, if necessary.

**The April 22, 2003 Restriction Requirement**

The Office Action mailed April 22, 2003, divided the claims into 10 groups. The claims are appended for the convenience of the Commissioner (claims as amended in the response filed on May 22, 2003 are attached in an Appendix).

In the response filed May 22, 2003, applicants elected for prosecution group I.

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claims 1-4, 5-9, and 15-16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through nucleic acid analysis. The applicants elected Pax 2 protein as the species for the prosecution of the Group II-X claims. Claim 38 was canceled. The claims as proposed to be amended in the response filed on May 22, 2003, correct multi-dependency.

Group II included claims 1-4, 10, 11 and 13-16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through protein analysis;

Group III included claims 1-4, 10-13, 15 and 16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through antibody analysis;

Group IV included claims 17, 18, 21 and 22, drawn to a method of using a specific agent to determine the level of a nucleic acid;

Group V included claims 17, 19 and 20-22, drawn to a method of using a specific agent to determine the level of a protein;

Group VI included claim 23, drawn to a kit for detecting nucleic acids;

Group VII included claim 23, drawn to a kit for detecting proteins;

Group VIII included claims 24-29 and 37, drawn to a method of treating prostate cancer through nucleic acid administration;

Group IX included claims 30-35, drawn to a nucleic acid construct; and

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Group X included claims 36 and 38, drawn to a pharmaceutical composition for treating prostate cancer.

Claims 1-16 and 37 are drawn to a method of determining the susceptibility of, diagnosing or predicting the relative prospects of a particular outcome of prostate cancer by determining the level of Pax 2 protein or nucleic acid. Claims 17-22 are drawn to the use of an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid. Claim 23 is drawn to a kit comprising an agent is capable of use in determining the level of Pax 2 protein or nucleic acid and a control sample. Claims 24-28 are drawn to a method of treating prostate cancer in a patient comprising the step of administering to the patient an agent which selectively prevents the function of Pax 2. Claim 29 is drawn to use of an agent which selectively prevents the function of Pax 2 in the manufacture of a medicament for treating prostate cancer. Claims 30-36 are drawn to a genetic construct and a pharmaceutical composition comprising a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell.

It is well established that the same claims cannot be divided into separate inventions. The examiner therefore clearly erred when he placed claims 1-16 into three separate groups, and claims 17-22 into two groups.

This application is a U.S. filing of a PCT application. Under PCT Rule 13, if the claims are so linked as to form a single general inventive concept, a lack of unity of

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invention objection is improper (See PCT Rule 13; see also MPEP § 1893.03(d)). The Examiner imposed the restriction on the basis that the claims are drawn to **nucleic acids, proteins and antibodies** with no consideration of the relationships between the specific nucleic acids, proteins and antibodies defined in the claims. This is clearly improper. The novel and inventive feature of the claims are **Pax 2 proteins, nucleic acids, or antibodies to the proteins** rather than proteins nucleic acids, or antibodies at large. As described at p. 5, line 25 to p. 6, line 4 and p. 57, line 25 to p. 65, line 9 (Example 1), the applicants found in the first time that Pax 2 protein is associated with prostate cancer. This finding led the applicants to make and use the compositions and methods for determining the susceptibility, diagnosing, and treating prostate cancer, which requires the determination of the level of the Pax 2 protein, nucleic acid, or an antibody to the Pax 2 protein.

Contrary to the Examiner's assertion, the proteins, nucleic acids and antibodies recited or encompassed in the claims share a common technical feature as required by PCT Rule 13.2. One of ordinary skill in the art would recognize that the Pax 2 protein, nucleic acid, and the antibody to the protein are specifically interrelated. One of ordinary skill in the art would appreciate that the PAX 2 nucleic acid dictates the composition and structure of the Pax 2 protein, which, by definition, dictates the structure and composition of its antibody. Therefore, this technical feature provides unity to claims 1-37, including the alternatives Pax 2 proteins, nucleic acids, and

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antibodies according to PCT Rule 13.2 (see PCT Article 3(4)(iii) and 17(3)(a), PCT Rules 3.1 and 13.2; see also MPEP §1850, particularly §1850(D)). As such, the restriction requirement is clearly improper.

Claims must be both patentably distinct and independent in order to be subject to restriction requirement. Definitions are provided by CHISUM 4:12.03[1]: The Patent and Trademark Office defines "independent" as meaning "not dependent," which in turn means "there is no disclosed relationship between the two or more subjects disclosed." Examples include species not usable together as disclosed or process and apparatus incapable of being used in practicing the process. The Office cites the extreme example of a shoe and a locomotive bearing. The Office defines "distinct" as meaning related or dependent but "capable of separate manufacture, use or sale as claimed" and "patentable over each other." Examples of dependent and distinct inventions include combination and subcombination, process and apparatus, process and product, and composition and process of use under appropriate circumstances.

In an election of species, only the elected species is initially examined. Once this claim is determined to be allowable, the examiner must search the remaining species.

Further, the MPEP states that species, "while usually independent, may be related under the particular disclosure. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction

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must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP 806.05-806.05(i)." (MPEP 806.04(b))

The MPEP provides that if an applicant discloses multiple species but includes only generic claims, election between species is normally not required. If an applicant discloses multiple species and includes claims restricted to those species, the applicant will be required to elect one species. He will then be restricted to those claims that read on that elected species unless a generic claim is found to be allowable. In the latter event, the applicant may include further claims to additional species (up to a reasonable number) provided that such additional claims "are written in dependent form (Rule 75), or otherwise include all the limitations of the generic claim."

The restriction requirement, by creating separate inventions out of the generic claims, makes it impossible to examine the claims in their entirety, and forces the applicants to restrict it to a single species.

The examiner has no legal authority to require applicants to restrict a generic claim to a single species, absent prior art or lack of enablement.

**Summary**

The current restriction imposed on the claims of the present invention is improper. This restriction is inconsistent with the guidelines for restriction practice delineated by the MPEP and PCT rules. Upholding this restriction requirement would

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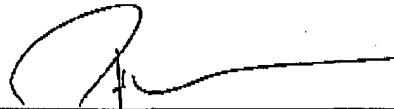
Filed: August 20, 2001

PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

be to allow the examiner to impose limitations on the claims *which are not now present.*

Favorable consideration of this petition is earnestly solicited.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Date: October 1, 2003  
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PETITION FOR RECONSIDERATION OF RESTRICTION REQUIREMENT

**APPENDIX:** *Clean Copy of Claims as Pending*

1. (original) A method of determining the susceptibility of a human patient to prostate cancer comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.

2. (original) A method of diagnosing prostate cancer in a human patient comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.

3. (original) A method of predicting the relative prospects of a particular outcome of prostate cancer in a human patient comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.

4. (currently amended) A method according to any of claims 1, 2 or 3 wherein the cancer is invasive.

5. (currently amended) A method according to wherein the sample contains nucleic acid and the level of Pax 2 nucleic acid is measured by contacting the nucleic acid with a nucleic acid which hybridises selectively to Pax 2 nucleic acid.

6. (original) A method according to claim 5 wherein the sample contains

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mRNA and the nucleic acid selectively hybridises to Pax 2 mRNA.

7. (currently amended) A method according to claim 5 or 6 wherein the nucleic acid which hybridises is detectably labelled.

8. (currently amended) A method according to claim 5 wherein the nucleic acid which selectively hybridises is detectably labelled.

9. (currently amended) A method according to claim 5 wherein the nucleic acid which selectively hybridises is suitable for use in a nucleic acid amplification reaction.

10. (currently amended) A method according to any of claims 1, 2 or 3 wherein the sample contains protein and the level of Pax 2 protein is measured.

11. (original) A method according to claim 10 wherein the level of protein is measured by contacting the protein with a molecule which selectively binds to Pax 2 protein.

12. (original) A method according to claim 11 wherein the selective binding molecule is an antibody or fragment or derivative thereof or an antibody-like molecule.

13. (original) A method according to claim 11 or 12 wherein the selective binding molecule comprises a detectable label.

14. (original) A method according to claim 10 wherein the level of Pax 2 is measured by selectively assaying its activity in the sample.

15. (currently amended) A method according to any of claims 1, 2 or 3 wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which

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prostate cancer may be or has been found, or contains cells from said tissue.

16. (original) A method according to claim 15 wherein the sample is any one of urine, semen, blood or lymphatic circulation.

17. (currently amended) A method of diagnosing prostate cancer comprising administering an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid in a sample in the manufacture of a reagent for diagnosing prostate cancer.

18. (currently amended) The method of claim 17 wherein the agent is a nucleic acid which selectively hybridises to Pax 2 nucleic acid.

19. (currently amended) The method of claim 18 wherein the agent is a molecule which selectively binds to Pax 2 protein.

20. (currently amended) The method of claim 19 wherein the agent is useful in selectively assaying the activity of Pax 2 protein.

23. (currently amended) A kit for diagnosing prostate cancer comprising an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid in a sample and a control sample wherein the control sample may be a negative control not comprising a detectable amount of Pax 2 nucleic acid or protein, or it may be a positive control comprising a detectable amount of Pax 2 nucleic acid or protein.

24. (original) A method of treating prostate cancer comprising the step of administering to the patient an agent which selectively prevents the function of Pax 2.

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25. (original) A method according to claim 24 wherein the agent prevents the expression of Pax 2.

26. (original) A method according to claim 24 wherein the agent inhibits the activity of Pax 2.

27. (original) A method according to claim 26 wherein the agent is an antisense molecule.

28. (original) A method according to claim 26 wherein the agent is a ribozyme.

29. (currently amended) A method of treating prostate cancer comprising administering an agent which selectively prevents the function of Pax2.

30. (original) A genetic construct a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell.

31. (original) A genetic construct according to claim 30 adapted for delivery to a human prostate cell.

32. (original) A genetic construct according to claim 31 wherein the adaptation allows delivery to a prostate cancer cell.

33. (currently amended) A genetic construct according to claim 31 comprising means to selectively deliver the nucleic acid to a prostate cancer cell.

34. (currently amended) A genetic construct according to claim 30 comprising means to selectively express the nucleic acid encoding a molecule in a prostate cancer cell.

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36. (currently amended) A pharmaceutical composition comprising a genetic construct comprising a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell and a pharmaceutically acceptable carrier.

37. (currently amended) The method of claim 2 wherein the step of determining whether the sample contains a level of Pax 2 protein associated with prostate cancer is carried out using western blotting.

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